



GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket No. 98N-0359
Program Priorities in the Center for Food Safety and Applied Nutrition;
Request for Comments

The Grocery Manufacturers of America, Inc. (GMA) wishes to submit the following comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for the year 2000.

GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than \$450 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

Before presenting our detailed comments, GMA wishes to compliment the priority setting process which Mr. Levitt has instituted at the Food and Drug Administration's CFSAN. It has been a helpful and open process which allows input from all stakeholders. Once defined the program priorities have been a very useful aid in keeping focus and accountability during implementation. Finally, the periodic summary of the achievements show that the process is working to get priority tasks completed. Further, the addition of new "A" priority items during the 1999 calendar year show the process is a living vital one that accommodates new priority information in a timely fashion.

GMA addresses below the questions FDA requests comment on in reference to the CFSAN 2000 Program Priorities:

1. With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?

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- a) While addressed in 1999 priorities, greater emphasis should be put on microbial risk assessments, e.g. *Listeria monocytogenes*, in relation to foods which are eaten without a “kill step”. This issue is an active one for domestic consideration as well as internationally, e.g. in Codex.
- b) Full expedited support should be given to existing and imminent petitions for the expanded safe use of irradiation/electronic pasteurization.
- c) Greater emphasis should be given to bring closure to the regulatory issues which represent unnecessary barriers to responsible sale of dietary supplements.
- d) One issue that seems to be missing from the Domestic Surveillance and Outbreak Response Coordination efforts is a set of guidelines for timely communication by FDA/CDC/State/Etc. with a manufacturer of a suspect product. Similar guidelines should be defined for when communication is appropriate with the public and what scientific threshold needs to be met.
- e) Educational efforts for safe food handling need to be further strengthened especially for children and high risk populations as the 1999 priorities addressed.
- f) Foods derived from biotechnology which have been approved by FDA as safe after rigorous scientific studies need to be confirmed by FDA to other governments, the media, and some consumers when critical questions are brought forward based on lack of information or misinformation.

2. Within the 10 program areas identified previously, what specific activities do you believe should be top priorities for CFSAN and why?

- a) A strong science-based surveillance system will provide the best database for identifying serious illness outbreaks so that action can be taken to minimize illnesses and prevent future ones. Recent reports indicate that the interagency groups are collecting better quality and quantity of such information so that indicated actions by government and industry can more confidently be taken to minimize or eliminate such occurrences.
- b) Food safety education for food handlers in foodservice, food retail, and the home continues to be high priority because a preponderance of the incidents trace to breakdowns at these levels.
- c) Risk assessments, particularly for common pathogens, are critical to addressing the real world risks associated with foods which do not contain a kill step.
- d) Full implementation of those areas where mandatory HACCP has been initiated.
- e) Research programs on food safety, particularly those being planned in the Three Year Plan for Research in Support of the National Food Safety Initiative, including those being initiated at JIFSAN. Use of leveraged research on food safety is also important, e.g. Extramural and USDA.
- f) Utilizing the full authority to inspect imports for food safety both domestically as well as in the exporting country.

- g) Continue expedited review for food additives as well as the timely completion of reviews for other food additive and color petitions. It may be helpful to link the previous B-2 priority, i.e. identify efficiencies/streamlining mechanisms for the food additive review process.
- h) Continue to review nutrient content/health claim notifications and petitions within statutory review times.
- i) Review premarket notifications for supplements containing new dietary ingredients within statutory timeframes.
- j) Develop overall strategy for achieving effective regulation of dietary supplements under DSHEA.
- k) Complete work on patulin in apples used for juice and continue process to get the required data to do a risk assessment of fumonisin.
- l) GMA will make no comment on the cosmetic priorities.
- m) Continue focused food safety research at NCFST and JIFSAN. Review (including peer review) all research for relevance to CFSAN's regulatory mission and priorities.
- n) Strengthening the scientific expertise across the Center's regulatory programs will make CFSAN more efficient and effective in delivering against the needs of the consumer and the food industry.
- o) A well integrated food safety system that includes FDA, CDC, USDA, and state & local governments needs to move further toward a reality.
- p) FDA has done a good job this year in defining the top priorities in the international arena and has a separate document out for comment on that subject itself. The key issues are food safety and trade issues in Codex, WTO/SPS/TBT, NAFTA, and others. Greater implementation of bilateral and multilateral equivalency determinations of exporting country food safety systems should be made.
- q) In the area of human resources the 1999 priorities are appropriate and several hopefully can move to full implementation. Training and communication are critical to a healthy productive organization.

3. FDA needs to ensure that its research programs provide the scientific information upon which regulatory decisions are made. In CFSAN, what do you believe should be the highest priority areas for conducting research?

- a) Development of rapid accurate pathogen analyses for food matrices
- b) Prevention techniques for pathogen avoidance, reduction, and elimination
- c) Risk assessment methodologies: microbial exposure models, dose response models, new food process modeling techniques assessments.
- d) Determination of levels of pathogenic microorganisms in specific commodities that would not pose a risk to specific high risk populations.
- e) Contamination of grain-based products with mycotoxins.

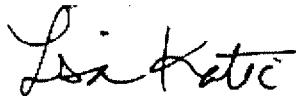
4. Because so much of our nation's food supply is either imported or exported, what do you believe should be the highest priority international activities?

- a) Monitor imported food and inspect foreign establishments exporting to the U.S.
- b) Work in various international organizations toward international harmonization in order to facilitate free trade in foods and assure safe foods for consumers.
- c) Work with exporting countries to evaluate their equivalency with respect to their food safety systems and provide associated technical assistance.
- d) Take an active role in the U.S. Government activities in the food trade area, e.g. WTO, SPS, TBT, via USTR, etc.

This completes our comments on the CFSAN 2000 Program Priorities. GMA would be happy to discuss any of our comments further in the future to expand or clarify our positions.

Thank you for the opportunity to participate in this process. We look forward to seeing the final priorities for January – September, 2000.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa Katic". The signature is fluid and cursive, with the first name "Lisa" and last name "Katic" clearly distinguishable.

Lisa Katic, R.D.
Director, Scientific and Nutrition Policy